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Beware of the Siren Song of 'Free Trade' in Drug Importation Proposals

Executive Summary

- Some Senators argue that the current ban on the importation of prescription drugs should be lifted because it prevents American consumers from obtaining patented drugs at lower prices from other nations. Some often couch their argument in the language of "free trade," suggesting that their goal is simply to allow prescription drugs to flow across borders in roughly the same manner as do other tradeable goods.
- However, S. 334 "The Pharmaceutical Market Access and Drug Safety Act of 2005," amounts to anything but free trade. S. 334 would not only lift the ban on importation, but would **compel** drug companies to sell sufficient quantities of drugs in other countries to supply resale needs in the U.S. market.
- Patented prescription drug prices are lower in other nations because of price controls. And so, compulsory drug importation would not represent free trade at all, but, rather, the importation of other countries' price controls.
- Some Senators who support the compulsory importation of price-controlled drugs advocate a very different trade policy when it comes to government pricing practices they find unfair, such as the Canadian Wheat Board's regulation of the export price of its western wheat, or the "stumpage" fees the Canadian government charges lumber companies.
- American consumers have more access to newer and more innovative medications than do consumers anywhere else in the world; generic drugs enter the market faster and are priced lower in the U.S. than in any other nation; and more research-based drug development occurs in the U.S. than anywhere else. The importation of price controls would reduce the financial incentive to invest in drug research and development (R&D), resulting in fewer medical breakthroughs and leaving U.S. consumers worse off in the long run.
- Congress should encourage the United States Trade Representative (USTR) to promote *real* free trade by pressing developed nations to eliminate price controls on innovative drugs. The USTR has already pursued this strategy in the U.S.-Australia Free Trade Act, and should push for further liberalization of drug pricing at the World Trade Organization (WTO) biennial ministerial meeting this December.

Introduction

In an effort to reduce the prices of prescription drugs in the United States, the Senate may soon consider a bill to allow the wholesale importation of prescription drugs from abroad. According to the Commerce Department's International Trade Administration (ITA), patented prescription drug prices are, on average, 18 percent to 67 percent less in foreign countries than in the U.S.[1] Proponents of importation argue that the current ban on the importation of prescription drugs should be lifted because it prevents American consumers from obtaining access to these lower prices.[2] Many supporters of this approach couch their argument in the language of "free trade," suggesting that their goal is simply to allow prescription drugs to flow across borders in roughly the same manner as do other tradeable goods.

The reality of their legislation, however, is anything but free trade. Their legislation relies on government coercion, among other things, to require drug companies to sell sufficient quantities of drugs in other countries to supply resale needs in the U.S. market. That is not free trade. Moreover, patented prescription drug prices are lower in other nations because of price controls, not lower-cost production methods or greater productivity.[3] And so, legalized drug importation would not represent free trade at all, but, rather, the importation of other countries' price controls. Instead of free trade, the result would be "parallel trade," where drug wholesalers would profit by diverting drugs intended for foreign markets to the United States.[4]

This is not just an academic distinction: to understand the difference between the two forms of trade is to recognize why drug importation would not benefit American consumers. Individuals who travel across the border to Canada or use a foreign pharmacy's website may be able to save significant sums on prescription drugs by buying foreign price-capped drugs directly. But if Congress were to permit large-scale drug importation, U.S. pharmacies and other intermediaries would bid away much of the fixed supply of foreign price-controlled drugs.[5] This would lead to drug shortages in foreign markets – an outcome the Canadian government has said it would prevent through legislative action to curb exports – and erode potential consumer savings once the shipping, repackaging, and administrative expenses (as well as trader and pharmacist profits) are taken into account.[6]

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[1] "Pharmaceutical Price Controls in OECD Countries, Implications for American Consumers, Pricing, Research and Development, and Innovation," International Trade Administration, U.S. Department of Commerce, December 2004.

[2] The Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits anyone other than the U.S. manufacturer of a prescription drug from importing that drug into the United States § 381(d)(1). The Secretary, however, is authorized to allow the importation of any drugs that are required for emergency medical care, and the FDA currently does not enforce this prohibition against individuals who import a limited supply of prescription drugs for personal use.

[3] Congressional Budget Office (CBO), "Would Prescription Drug Importation Reduce U.S. Drug Spending?" April 29, 2004.

[4] Drug importation would lead to "parallel trade." Under this arrangement, international wholesalers and intermediaries buy drugs in low-price nations and resell them in the U.S. to capture arbitrage profits. For further information on this dynamic, see: U.S. Senate Republican Policy Committee, "The Strange Fixation with Drug Importation: Who *Really* Wins?" August 19, 2004.

[5] CBO.

[6] American Health Line, "Canada Announces Plan to Ban Bulk Rx Exports," June 30, 2005.

S. 334 "The Pharmaceutical Market Access and Drug Safety Act of 2005" (sponsored by Senator Dorgan), would address the obstacle posed by inadequate foreign supplies by making it unlawful for drug companies to raise prices or limit supplies to foreign pharmacies or wholesalers that export to the United States.[7] By stripping drug companies of their commercial freedoms of sale and contract, the bill contradicts its sponsors' "free trade" intent.

If importing foreign price controls is such a good idea, why not just impose price controls domestically? It is likely that this strategy has not been pursued because it is well known that price controls would reduce the incentives for drug innovation, leaving U.S. consumers and health care worse off in the long run.[8] Yet, the importation of price controls would simply be a more circuitous route to the same policy.

The U.S. pharmaceutical market has achieved an impressive balance between innovation incentives and generic drug affordability: American consumers have more access to newer and more innovative medications than do consumers anywhere else in the world; generic drugs enter the market faster and are priced lower in the U.S. than in other nation; and more research-based drug development occurs in the U.S. than anywhere else. If Congress seeks to eliminate the international price differences that currently exist, U.S. consumers would be much better off if we *exported our own drug market* to other nations instead of importing theirs.

Congress should encourage the United States Trade Representative (USTR) to promote *real* free trade by disallowing developed nations from discriminating against innovative drugs under the guise of "public health" concerns. The USTR has already pursued this strategy in the U.S.-Australia Free Trade Act,[9] and should push for further liberalization of drug pricing at the World Trade Organization (WTO) biennial ministerial meeting this December. Eliminating the trade barriers posed by price controls would reduce drug prices and improve health outcomes in the U.S., and promote the growth of domestic jobs and investment provided by the U.S. pharmaceutical industry.

Free Trade versus Drug Importation

It is helpful to begin this analysis by reflecting on what "free trade" actually means. In its modern usage, free trade usually refers to commerce between nations that is unimpeded by government restrictions such as tariffs, export subsidies, domestic production subsidies, trade quotas, or import licenses.[10] Free trade has both practical and theoretic foundations. On a practical level, free trade provides consumers with the access to goods and services produced (or provided) in other nations without restriction. This gives consumers the option of purchasing foreign goods and services that might not otherwise be available in their domestic market, and provides competition to domestic businesses, which reduces the cost of goods and services and eases the burden on family budgets.

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[7] S. 334, Section 804(n). Senator Byron Dorgan, testimony before the U.S. Senate HELP Committee, April 19, 2005.

[8] James W. Hughes, Michael J. Moore, and Edward A. Snyder, "'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare," National Bureau of Economic Research (NBER), Working Paper 9229, September 2002.

[9] P.L. 108-286, Chapter 17.

[10] The Columbia Electronic Encyclopedia, Sixth Edition, Columbia University, 2003.

For centuries, free trade policies have also been embraced as a means to enhance overall economic efficiency and standards of living. In addition to providing consumers with lower prices for goods and services, the competition provided by open borders benefits the importing country by freeing its labor and capital resources to be devoted to more productive endeavors in which it enjoys a comparative advantage.[11] For example, as the U.S. has lowered import duties on appliances, electronics, and automobiles, domestic investment and employment opportunities have shifted to areas of high technology such as software, microprocessor design, telecommunications, and research-based pharmaceuticals.[12] This process has led to higher wages for American workers, greater purchasing power for American consumers, and a more productive economy.[13]

By eliminating the distortions of investment and production caused by protectionist policies, free trade raises living standards. Federal Reserve Chairman Alan Greenspan has observed that, by expanding markets and enhancing competition, free trade has "rendered many forms of government intervention either ineffective or perverse."[14] When the government permits goods that can be grown or produced less expensively in foreign countries to enter the U.S. market, the cash flows of industries employing "older, increasingly obsolescent technologies" are used to finance investment in new technologies. Through this process, "wealth is created, incremental step by incremental step."[15]

Drug Importation Replaces Market Competition with Government Regulation

By contrast, the "free trade" in prescription drugs envisioned by some policymakers would not produce any of the economic efficiency gains or increases in living standards associated with free trade. In fact, importation would actually subvert the wealth-creating potential of trade *by replacing market competition with government regulation.*

Drug importation would not deliver economic efficiency gains because drugmakers are already legally permitted to "take advantage of any lower-cost foreign manufacturing environments."[16] This means that drug importation would involve "no new prospect of savings in production" and, according to the Congressional Budget Office (CBO), would leave "the cost of producing pharmaceutical innovations unchanged."[17] Ironically, the additional regulatory burden imposed by S. 334 to protect consumer safety would necessarily result in an increase in manufacturers' total cost of production relative to current law.[18]

The prices of patented drugs in foreign markets are lower than those in the U.S. as a result of the intervention of foreign governments. The specifics of the intervention vary by nation. Some governments directly purchase drugs; others impose explicit limits on

[11] S. Hollander, *The Economics of David Ricardo*, University of Toronto Press, 1979.
[12] Chairman Alan Greenspan, testimony before the Senate Committee on Finance, April 4, 2001.
[13] Steven Landefeld and Barbara M. Fraumeni, "Measuring the New Economy," *Survey of Current Business*, Bureau of Economic Analysis, March 2001.
[14] Greenspan.
[15] Greenspan.
[16] CBO.
[17] CBO.
[18] S. 334, Section 804 (e) and (f).

pharmaceutical profits. Others use reference pricing (where a new drug is priced equivalent to similar drugs irrespective of its efficacy), or more subtle forms of pricing regulation, such as approval delays, procedural barriers, and restrictions on dispensing and prescribing.[19] According to the ITA, government intervention caused annual revenues of research-based drug companies in 11 developed nations to be $18 billion to $27 billion lower (25 percent to 38 percent) than would have been the case without price controls.[20]

Drug Companies and Foreign Governments Have Incentives to Subvert Importation

Under current law, the importation of pharmaceuticals to the United States is limited to the holder of the patent.[21] Drug importation schemes would lift the current prohibition, and allow anyone to import patented drugs. However, simply permitting unlicensed drug importation would not, in and of itself, lead to importation on a large scale because both drug originators and foreign governments would have strong incentives to prevent it.

For example, drug companies concerned about the loss of sales to foreign exporters could insert language into contracts prohibiting foreign wholesalers from reselling drugs to U.S. consumers, or limit the supply of drugs entering foreign markets if orders appear to exceed local needs.[22] Drug companies could also preempt importation by altering the color, size, shape, or dosage of their exports or by shifting foreign production to plants not specifically registered with the Food and Drug Administration (FDA).[23] Such actions would make drugs ineligible for import into the United States.

Foreign governments concerned about importation's effects on local drug supplies could respond likewise by imposing statutory bans on exports, or by pressuring drug wholesalers from exporting drugs to the United States. Indeed, this June the Canadian Health Minister announced that Canada plans to take legislative action to ban bulk exports of prescription drugs to the United States in the event of a domestic shortage.[24]

Supporters of S. 334 Would Prevent 'Free Market' Responses

Aware that these likely market responses would undermine the wholesale importation they seek, the sponsors of S. 334 have included language to *compel* importation from every market in which a particular drug is sold. While supporters of S. 334 contend that they only seek "free trade," their legislation regards drug companies' freedom of contract and sale – the two essential elements of free trade – as "loopholes" that must be closed. Specifically, S. 334 would:

- prevent drug companies from raising prices charged to a foreign pharmacy or wholesaler that exports drugs to the United States relative to a foreign pharmacy that sells drugs domestically;

[19] International Trade Administration (ITA).
[20] ITA. The 11 countries in the study were Australia, Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Spain, Sweden, and the United Kingdom. The estimate is based on the assumption that drug prices between nations would still differ, but such differences would be explained by differences in per-capita income.
[21] *Fuji Photo Film v. Jazz Photo.*, 394 F.3d 1368 (Fed. Cir. 2005).
[22] CBO.
[23] CBO.
[24] American Health Line, "Canada Announces Plan to Ban Bulk Rx Exports," June 30, 2005.

- prevent drug companies from discriminating against, or otherwise refusing to do business with, a foreign pharmacy or wholesaler that exports drugs to the United States by denying, restricting, delaying, or reducing their drug supply by making such action "an unfair and discriminatory practice, subject to treble economic damages";
- prohibit a drug originator from changing the color, an inactive ingredient, or place of manufacture of the drug so that it is no longer FDA-approved to ensure "all imported drugs will be FDA-approved, while also ensuring there will be drugs to import"; and
- immunize pharmacies, wholesalers, and individuals from patent damages that would otherwise arise from the unauthorized importation of drugs.[25]

Taken together, these provisions of S. 334 would allow a foreign drug wholesaler to fill orders for a nearly limitless supply of patented drugs, resell those drugs in the United States at a profit, and make it illegal for a U.S. drug manufacturer to take action to limit the scale of the foreign wholesaler's risk-free profiteering.[26] Clearly, the commercial restrictions necessary to produce parallel trade in prescription drugs stand in sharp contrast to free trade, which depends on a reduction of government intervention.

Recognizing that compelling a U.S. drug company to make foreign sales it does not wish to make would not only violate the most basic principles of free trade, but also the U.S. Constitution,[27] S. 334 states that the bill "applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing . . . shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country."[28] Essentially, this provision would force U.S. drug companies to either forego the supplementary revenues available from drug sales in foreign countries, or allow foreign drug wholesalers to import price controls to the United States. Clearly, invoking the name of "free trade" for such a Hobson's choice is entirely inappropriate. Free trade cannot mean that the exporter will be subjected to government regulation unless he chooses to forego trade.

Policymakers Can't Have it Both Ways: A Look at Trade Policies with Wheat and Wood

Beyond forcing drug originators to choose between limiting their international sales of prescription drugs or surrendering their commercial freedoms in the United States, S. 334 is deeply troubling on another front in that it would implicitly accept the often protectionist drug-regulatory regimes of other nations. By compelling parallel trading in price-controlled drugs, S. 334 affirmatively embraces such protectionism. Policymakers need to recognize that this is the other side of the free-trade coin, and that they can't rationally have it both ways. Yet, when foreign governments intervene to set prices for goods exported to the U.S. market, many Senators (including some of the sponsors of S. 334) are quick to object.

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[25] S. 334, Section 804(n). Senator Byron Dorgan, testimony before the U.S. Senate HELP Committee, April 19, 2005.

[26] Roger Pilon, Vice President, CATO Institute, testimony before U.S. Senate Special Committee on Aging, January 26. 2005. "Designed generally to prohibit companies from raising prices or limiting supplies abroad, such measures are likely unconstitutional; and if not, they truly would amount to importing foreign price controls. If that's what we want, then apply controls directly."

[27] Thomas Arthur, testimony before the U.S. Senate HELP Committee, April 19, 2005.

[28] S. 334, Section 804(n)(3)(A).

For example, some Senators have vocally opposed the Canadian Wheat Board (CWB),[29] which sets prices for Canadian wheat – yet, it is not unlike Canada's Patented Medicine Prices Review Board, which sets prices for drugs sold in Canada.[30] In a 2002 letter to the USTR, Senator Dorgan and other Senators argued forcefully for the imposition of tariff rate quotas on Canadian wheat imports to combat the CWB's "unfair" pricing practices.[31] In 2003, the Commerce Department responded by imposing tariffs on Canadian hard red spring wheat in response to the alleged dumping, but the legality of these tariffs has been called into question and is currently being adjudicated before a North American Free Trade Agreement (NAFTA) dispute resolution panel.[32]

Similarly, many Senators support tariffs on imports of Canadian softwood lumber because they believe the "stumpage" fees charged by the Canadian government to be too low, and represent an unfair trade subsidy.[33] As of this April, Canada has won eight consecutive victories before NAFTA and WTO dispute resolution panels that have investigated the subsidy claims.[34] Yet some Senators not only continue to insist that Canadian lumber benefits from unfair government pricing practices, but also urge the U.S. Treasury to distribute to U.S. lumber companies the estimated $3.6 billion in duties already collected on Canadian imports.[35] The WTO is expected to rule later this year as to whether Canada can legally retaliate against other U.S. exports to Canada if the tariffs are left in place, or if the paid duties held by the Treasury are distributed.[36]

Price Controls Destroy R&D Incentives

By embracing unfair pricing practices on pharmaceuticals that many Senators would never accept for imported wheat or lumber, S. 334 would undermine U.S. patent law and the commercial incentives to invest in new drug development.[37] Pharmaceutical patents effectively prevent competition in the sale or manufacture of the patented molecular entity from developing

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[29] The Canadian Wheat Board, "About us," available at: http://www.cwb.ca/en/about/index.jsp.
[30] About the PMPRB, available at: http://www.pmprb-cepmb.gc.ca/english/View.asp?x=175&mp=87.
[31] Letter to the USTR, March 14, 2002. Available at: http://dorgan.senate.gov/newsroom/extras/2074114.pdf. Senator Dorgan argues that the CWB is a "government-sanctioned monopoly" that has "deeply subsidized Canadian grain," and artificially boosted exports to undercut U.S. farmers. "U.S. Seeks WTO Coalition Against Canadian Wheat Board Practices," Office of International Information Programs, U.S. Department of State, April 19, 2002.
[32] "NAFTA Orders U.S. to Recalculate Part of Canadian Wheat Tariff," AP, March 14, 2005.
[33] USTR, USTR Wins Key Issues in WTO Softwood Lumber Appeal, January 19, 2004. Available at: http://www.ustr.gov/Document_Library/Press_Releases/2004/January/US_Wins_Key_Issues_in_WTO_Softwood_Lumber_Appeal.html.
[34] Blakes Bulletin on International Trade, "Observations on Canada-U.S. Trade Relations in 2005," April 2005.
[35] *Vancouver Sun*, "U.S. Senator Proposes to 'Liquidate' $3.6 Billion in Softwood Duties," November 18, 2004.
[36] Blakes Bulletin.
[37] Patent rights are as old as the American Republic itself. Article I, Section 8, Clause 8 of the Constitution explicitly vests Congress with the power "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Current patent law is based upon the Patent Act of 1952, codified in Title 35 of the United States Code. This statute allows inventors to obtain patents on processes, machines, manufactures, and compositions of matter that are useful, new, and nonobvious. Granted patents confer the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.

until the patent expires.[38] Earlier this year, the U.S. Court of Appeals for the Federal Circuit confirmed that this protection extends beyond rival drug firms to include foreign wholesalers and pharmacies, even if the patent holder itself had first sold those goods outside the United States.[39]

Patents clearly represent a significant restriction on commercial freedom and competition. But this restriction is necessary to entice private, profit-maximizing firms to make the investments necessary to bring new innovative medicines to the market.[40] By effectively having been awarded a temporary monopoly, U.S. patent holders have the freedom to set prices in a manner that will maximize returns. Both economic theory and empirical evidence indicate that it is the potential for temporary monopolistic returns that induces research and development (R&D) expenditures for new drug innovations.[41]

According to two recent studies of differing methodology, the average cost to develop a new drug is between $801 million and $1.7 *billion*.[42] If a drug developer's commercial rivals were permitted to reproduce and sell a new drug at the time of its launch, the resulting competition would reduce the market price of the drug to a level consistent with the cost of producing additional units of the drug (marginal cost), which typically represent a small fraction of the total costs. As was said in Senate testimony, "the first pill is enormously expensive; the second costs almost nothing to produce."[43] As a result, competition would leave the innovator unable to recoup its up-front development outlays.[44]

Yet, to some supporters of S. 334, there is no rationale for the market-based prices Americans pay for innovative drugs, aside from corporate exploitation. As Senator Dorgan reasoned in Senate testimony, S. 334 "only allows importation from other major industrialized nations, and I don't think any of us believe the drug industry is actually selling its products for a loss in these countries. In other words, the drug companies have already voluntarily sold their medicines for a profit once."[45]

But this reasoning ignores the economics of drug production: the first pill could never be sold at anything but a loss; the millionth dose may cost less than 50 cents to produce and could

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[38] Wendy H. Schacht and John R. Thomas, "Patent Law and Its Application to the Pharmaceutical Industry," *Congressional Research Service*, RL30756, January 10, 2005. Pharmaceutical patent law is governed by the provisions outlined in the "Drug Price Competition and Patent Term Restoration Act of 1984" (P.L. 98-147, Hatch-Waxman) and the amendments made to it by Title XI of the "Medicare Prescription Drug and Modernization Act of 2003" (P.L. 108-173).

[39] *Fuji Photo Film v. Jazz Photo*.

[40] "Pharmaceutical Price Controls in OECD Countries, Implications for American Consumers, Pricing, Research and Development, and Innovation," International Trade Administration, U.S. Department of Commerce, December 2004.

[41] Thomas Abbott and John Vernon, "The Cost of U.S. Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions," NBER, Working Paper 11114, February 2005.

[42] The Tufts Center for the Study of Drug Development, November 30, 2001, and James Gilbert, Preston Henske, and Ashish Singh, "Rebuilding Big PhRma's Business Model," November 1, 2003.

[43] Roger Pilon, testimony before the U.S. Senate, Special Committee on Aging, January 26, 2005.

[44] James W. Hughes, Michael J. Moore, and Edward A. Snyder, "'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare," National Bureau of Economic Research (NBER), Working Paper 9229, September 2002.

[45] Senator Dorgan.

be sold profitably at the most miserly reimbursement rate of the "major industrialized nations." To use the production cost of the millionth dose as the basis for assessing a drug sale's profitability surely invites policies hostile to future research and development of new drugs.

Parallel Trade in Drugs Has Badly Damaged the European Drug Industry

Parallel trading has engendered precisely such hostility in Europe. Although price controls on pharmaceuticals have existed in Europe since 1957,[46] parallel trade has been a feature of EU drug markets only since the mid 1990s.[47] By allowing purchasers in higher-income EU member states (particularly governments) to acquire drugs from parallel importers in low-priced nations, parallel trade has created price competition among drug *regulators* instead of drug *developers*. The predictable consequence of inter-government competition to set lower prices has been the steady erosion of the European drug R&D industry.

In 1990, European pharmaceutical firms outspent their U.S. counterparts on R&D, $9.9 billion compared to $6.2 billion, but by 2000, U.S. pharmaceutical research firms outspent their EU counterparts, $29.9 billion to $21.1 billion.[48] In 2004, domestic U.S. drug R&D expenditures have increased to $30.6 billion, while foreign-lab R&D has stagnated.[49] Not surprisingly, this swing in R&D has led to a corresponding change in the location for new drug development: In 1988, Americans developed only 19 of the 50 best-selling drugs worldwide, but by 2003, American firms developed 15 of the top 20 best-selling drugs worldwide and 14 of the top 15 biotechnology drugs.[50]

Furthermore, European-headquartered pharmaceutical companies have shifted their own research to the United States due to their inability to generate sufficient revenues in their home markets. This year, only 59 percent of European-headquartered pharmaceutical firms' R&D is conducted throughout Europe, compared to more than 73 percent a decade ago.[51] This shift has boosted pharmaceutical industry jobs in the United States, and very good ones, at that. The industry now employs more than 1.1 million Americans, over 77,000 of whom are directly involved in the research and development of new drug compounds.[52] According to the Bureau of Labor Statistics (BLS), Americans in such professions earn a mean annual wage of between $68,730 and $71,730, which is almost twice the national average.[53]

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[46] W. Duncan Reekie, "Drug Price Controls: Regulation Without a Cause," International Intellectual Property Institute, available at: http://www.iipi.org/activities/forums/IP&Public_Health/papers/reekie%20paper.pdf.
[47] Patricia M. Danzon, "The Economics of Parallel Trade," *Pharmacoeconomics*, March 1998. Enforcement of the Treaty of Rome allowed parallel imports from traditionally low-priced countries, such as Spain, Portugal, and Greece to begin circulating freely in the European market.
[48] John E. Calfee, American Enterprise Institute, testimony before the Senate Committee on Finance, April 27, 2004.
[49] Pharmaceutical Research and Manufacturers of America, "Pharmaceutical Industry Profile 2005 - From Laboratory to Patient: Pathways to Biopharmaceutical Innovation," March 2005.
[50] Dr. David Gratzer, "Price Controls Stifle Drug Development," *Chicago Sun-Times*, September 14, 2003.
[51] Geoff Dyer, "The Wrong Diagnosis: National Champions May Not Cure the Ills of the European Drug Industry," *Financial Times*, May 5, 2004.
[52] Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2005.
[53] BLS, "National Occupational Employment and Wage Estimates Life, Physical, and Social Science Occupations," May 2004.

Importantly, drug R&D not only provides American jobs, but also, according to the Federal Reserve Bank of San Francisco, contributes to the "productivity of nearby organizations."[54] The process of scientific investigation and discovery produces important "spillover effects" that enhance the innovation of nearby businesses. Accordingly, "if firms relocated their R&D labs to countries outside the United States, because of restrictions on research or a shortage of U.S. scientists, then the United States would lose jobs as well as these knowledge spillovers, making the remaining firms less productive."[55]

Drug R&D is precisely the type of post-industrial, information-based economic activity that policymakers have been touting as America's future since the late-1990s. Yet, some would not only tolerate foreign attempts to undermine the industry's success, but actually import their destructive policies through mandated parallel trading.

Price Controls Reduce Access to Medicine

In addition to devastating new drug development, foreign price controls have dramatically reduced their citizens' access to innovative medications. Among the richest nations, the availability of FDA-approved medications ranges from 76 percent in Japan to 92 percent in France and 98 percent in the United Kingdom.[56] However, when drug availability is broken down by the age of the molecule, the restrictive effects of drug regulation become apparent.

The table below, constructed by Patricia M. Danzon and Michael F. Furukawa of the University of Pennsylvania's Wharton School, demonstrates a clear phenomenon for non-U.S. patients, even in high-income nations: *foreign patients have markedly less access to newer drugs*. The table depicts foreign countries' per-capita consumption of drugs by age relative to U.S. per-capita consumption. It is interesting to note that, although overall per-capita drug consumption in the United Kingdom is 115 percent of that in the United States, its per-capita consumption of drugs that have been on the market for two years or less is only 32 percent of U.S. consumption. Of the four other nations with total per-capita drug consumption levels equal to or greater than 75 percent of the U.S. level, only Germany's consumption of drugs less than two years old is greater than 50 percent of the U.S. level. Of drugs launched within the previous two to five years, only France, Germany, and Canada have per capita consumption levels greater than half that of the United States.

Foreign Drug Consumption by Age (U.S. Consumption Equals 100)

Molecule age	Canada	Chile	France	Germany	Italy	Japan	Mexico	U.K.
24 months or less	26	2	44	58	25	1	4	32
25–60 months	65	6	91	72	44	5	3	42
61–120 months	99	8	101	60	76	52	6	90
121 months or more	94	25	100	82	62	57	13	125
Total	91	22	97	78	62	53	12	115

[54] Margaret Kyle, "Does Locale Affect R&D Productivity?" *FRSB Economic Letter*, Number 2004-32, November 12, 2004.
[55] Kyle.
[56] Danzon and Furukawa.

As these drug consumption statistics make clear, foreign countries' price controls have created a system whereby *drug companies develop new drugs almost solely for the U.S. market, with additional supplies flowing to foreign markets to add supplementary returns as the drug nears the end of its period of market exclusivity.*

Generic Drugs are More Expensive in Foreign Markets

Given this dynamic – new drugs predominately developed in the U.S., and sold to U.S. consumers with foreign consumers left to consume older drugs at price-controlled rates – one would expect the United States to pay a disproportionately large share of its national income on prescription drugs relative to other nations. But this is not the case. According to the Organization for Economic Cooperation and Development's (OECD) *Health Data 2005*, the United States spends less of its national income on prescription drugs than France, and only slightly more than Italy.[57]

Prescription Drug Spending (as a % of GDP)			**Non-Drug Health Care Spending** (as a % of GDP)	
Slovak Rep.	2.27		US	13.07
Hungary	2.15		Switzerland	10.29
France	2.11		Germany	9.48
US	1.94		Norway	9.33
Italy	1.86		Iceland	8.98
Spain	1.68		Netherlands	8.68
Canada	1.67		Greece	8.32

Source: OECD Health Data 2005

As the table above demonstrates, as a percentage of Gross Domestic Product (GDP), U.S. drug consumption is far closer to the international average than U.S. consumption of all other forms of health care services, despite U.S. consumers' disproportionately high consumption of the newest and most costly medicines. It is interesting to consider that the United States actually spends far more of its income than other nations on non-prescription drug health care, but since these services (surgeries, diagnostic imaging, etc.) are not tradeable, they have been largely exempt from the current discussion and are beyond the scope of this paper.

The U.S. Generic Market Delivers Low-Cost Drugs to Consumers

The United States spends less of its income on prescription drugs, relative to some other industrialized nations because of the robust American generic drug market.[58] In the U.S., once a patent on a drug expires, generic manufacturers may enter the market and reproduce the same molecular entity in direct competition with the originator firm. To begin marketing the drug, generic competitors must simply submit an Abbreviated New Drug Application (ANDA) to the FDA. An ANDA allows a generic drug manufacturer to use the safety and efficacy data produced by the originator drug firm if the active ingredient of the generic drug is the bioequivalent of the approved drug. This process largely eliminates the costs and delays of the

[57] *OECD Health Data 2005*, June 8, 2005.
[58] Danzon and Chao.

normal drug approval process and often allows the generic firm to begin marketing its product immediately after the originator's patent expires.[59]

Although patents currently remain in effect for 20 years after the date the patent application was filed,[60] that does not translate into 20 years time on the market as a monopoly. Rather, as the table below indicates, in recent years the average drug only has had about 10 to 12 years of effective patent life remaining when it enters the market.[61] This time discrepancy is a product of FDA review times and clinical trials.

Average Effective Patent Length at Time of Commercial Launch[62]

Year	Shortest Duration	Longest Duration
1997	10.8	13.4
1998	13.0	15.0
1999	8.6	10.2
2000	8.3	11.9
2001	6.5	9.1
Average, 1997-2001	9.8	12.3

Once an originator's patent expires, its U.S. market share in the compound falls to 20 percent on average, with the average price of generic competitors about 70 percent to 90 percent below the originator's price prior to patent expiration.[63] On the whole, generic drugs now account for an estimated 58 percent of the total unit sales volume of U.S. prescriptions,[64] up from 17 percent in 1980.[65] Thus, the current U.S. regulatory system ensures that patients have access to less expensive generic drugs after a relatively short period of market exclusivity.

Off-Patent Drugs are More Expensive in Foreign Countries

By contrast, in foreign markets where the government-set price for a patented drug is particularly low, the margin between the capped drug price and the drug's reproduction cost is not sufficient to compel robust generic entry. As a result, the generic share of unit-sales volume remains low in France (28 percent), Italy (34 percent), and Japan (40 percent), relative to the United States. [66]

In addition to discouraging the entry of generics, some foreign governments "overspend" on the generics that are prescribed in their markets by purchasing "brand-name" generic drugs that compete on image rather than price. The ITA estimates that, by purchasing brand-name generic drugs instead of the unbranded, low-price generics sold in the United States, OECD countries "overspend" on generic drugs by as much as $30 billion per year.[67]

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[59] Schacht and Thomas.
[60] 35 U.S.C. § 154(a).
[61] Hughes, Moore, and Snyder.
[62] table constructed by Hughes, Moore, and Snyder
[63] Hughes, Moore, and Snyder.
[64] Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," *Health Affairs*, 2004.
[65] F.M. Scherer. *Industry Structure, Strategy, and Public Policy*, 1996.
[66] Danzon and Furukawa.
[67] ITA.

In the United States, where the generic sector is dominated by unbranded, less expensive products, generics comprise 58 percent of unit sales volume, but account for only 18 percent of total sales revenue.[68] By contrast, in Germany, the government supports the large number of German brand-name generic manufactures by paying higher reimbursement rates for their products.[69] As a result of such protectionism, the generic share of unit sales volume is 61 percent of prescriptions, but 34 percent of total sales revenue, which reflects inflated generic reimbursement rates. The same is true of Italy, where generics comprise 40 percent of prescriptions, but 21 percent of total drug sales revenue.[70] When coupled with the disincentive to generic entry, drugs with expired patents are *more expensive* in virtually all foreign nations than they are in the United States.[71]

A Better Way Forward: 'Export' the U.S. Drug Regime

Instead of embracing foreign drug control regimes, Congress should push for further liberalization of drug prices in foreign markets. In the Trade Act of 2002 (P.L. 107- 210), Congress instructed the USTR to seek increased transparency, consultative mechanisms, and reductions in non-tariff access barriers (price controls) for pharmaceuticals in future trade agreements.[72] The USTR followed this guidance by including specific provisions dealing with drug pricing in the U.S.-Australia Free Trade Agreement. During negotiations, the Australian government committed to the principle of "appropriately recognizing the value of innovative pharmaceuticals" by increasing the transparency of its drug pricing system and by agreeing to consult with pharmaceutical companies before making drug pricing and market access decisions.[73]

In addition to the U.S.-Australian Free Trade Agreement, the USTR has also made drug pricing and access a part of the U.S. trade dialogue with Canada, Japan, and Korea.[74] However, progress on this front has been limited because international trade rules put pharmaceuticals at a disadvantage relative to other goods. Commercial concerns are viewed as secondary to public health imperatives.

According to the WTO's Director-General, in the case of life-saving pharmaceuticals, the organization is bound to consider "humanitarian as well as trade concerns."[75] This has led the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement to provide for a number of circumstances under which states can choose to ignore patent rights to achieve vague "social goals."[76] WTO negotiations and declarations subsequent to the adoption of TRIPS

[68] Danzon and Furukawa.
[69] Espicom Healthcare Intelligence, "Germany Generics Market Intelligence Report," March 31, 2005.
[70] Danzon and Furukawa.
[71] ITA.
[72] Section 2102(b).
[73] William H. Cooper, "The U.S.-Australia Free Trade Agreement: Provisions and Implications," CRS Report for Congress RL32375, June 12, 2005.
[74] USTR, "U.S. Trade Agreements and Pharmaceuticals," July 8, 2004.
[75] "Decision removes final patent obstacle to cheap drug imports," WTO News, August 30, 2003.
[76] The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated in the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time.

have focused almost exclusively on ways to weaken patent rights to enhance less developed countries' access to low-cost medicine.[77] These directives have led Brazil to announce its intention to abrogate unilaterally the patent of Abbott Laboratories of Chicago unless it agrees to cut the price it charges for an HIV drug to below production costs.[78]

Efforts to ensure that poor nations enduring public-health crises have access to necessary medicine at low prices are laudable; but by treating patents as "obstacles" to access,[79] and viewing pharmaceutical company shareholders as a free source of trade subsidies, recent WTO directives have distracted trade negotiators from the equally important priority of drug development. The governments of developed nations have capitalized on this trend to impose commercial restrictions on drug imports that could never be countenanced in other markets.

Although the United States should continue to work with the WTO and its members to develop strategies to tackle health crises in poor nations, the USTR must not only include pharmaceutical pricing issues in bilateral negotiations and consultations, but also push for fundamental reform of the rules governing international trade in pharmaceuticals. The United States can simply no longer afford to treat prescription drugs as second-class tradeable goods, deserving of less protection from protectionist impulses than, say, soybeans or toy trucks.

Specifically, the United States should begin a dialogue at the December WTO Ministerial Meeting in Hong Kong to make the elimination of drug price controls in developed nations a goal of the trading body. The USTR should also recommend that foreign governments' expenditure on domestic generics be judged a violation of the "national treatment" provisions of Article 3 of the General Agreement on Tariffs and Trade (GATT).[80] Since much of foreign generic spending is used to benefit domestic industry at the expense of developers of new drugs, it is farcical to use "public health" exceptions to defend such trade distorting policies.

More Drugs, Lower Prices

Eliminating price controls in developed nations would provide long-term benefits to U.S. consumers in the form of improved health outcomes from the flow of new drugs and lower prices.[81] Based on ITA estimates, relaxation of foreign price controls and "appropriate reform of foreign generic markets" would lead to a "$5 billion to $8 billion" increase in annual worldwide R&D spending and three or four new molecular entities per year.[82] This could be accomplished without requiring foreign countries to spend more on drugs. Since, as explained above, foreign governments overspend on brand-name generics by as much as $30 billion per year, the ITA

It has been in effect since 1995 for all WTO members. WTO, "TRIPS and Pharmaceutical Patents," available at: http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm.

[77] The 2001 Doha Declaration and August 2003 directive allows governments to issue compulsory licenses to allow other companies to make a patented product or use a patented process under license without the consent of the patent owner and allows countries without the ability to produce drugs to import unlicensed generics.

[78] *The New York Times*, "Brazil to Copy AIDS Drug Made by Abbott," June 24, 2005.

[79] WTO News, "Decision Removes Final Patent Obstacle to Cheap Drug Imports," August 30, 2003.

[80] This principle of "giving others the same treatment as one's own nationals" is also found in all the three main WTO agreements (and Article 3 of TRIPS). Available at: http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm.

[81] ITA.

[82] ITA.

estimates that "a more competitive generic market could significantly, or even fully, offset" the cost of increasing the prices of on-patent drugs to competitive market levels.[83]

In addition to benefiting from new drugs, the elimination of price caps would also lower the prices of existing patented drugs through competition instead of regulation. Since patents only protect their holders from competition in the manufacture and sale of the very specific patented molecular entity, competing firms are free to develop (and apply for patents for) other compounds to treat the same illness, even if they were discovered through the application of research derived from previous patents.[84] As a result, many drugs still under patent protection face intense competition from other drugs in the same therapeutic class. Examples of such competition are the brand-name drugs Nexium, Prevacid, and Prilosec for the treatment of ulcers and acid reflux; similarly, doctors and their patients can choose between the brand-name drugs Lipitor, Zocor, and Vytorin for the treatment of high cholesterol.

Many drug developers choose to enter such markets because the risk associated with the development of only minor innovations (often referred to, pejoratively, as "me-too" drugs) is considerably lower.[85] With a much higher probability of successful development, "me-too" drugs often have a higher risk-adjusted return and are often used to fund the more speculative (and potentially higher yielding) drug research.[86] According to CBO, the first drug to enter a treatment category maintains its monopoly status for between one and six years after launch before a therapeutically similar patented drug enters the market.[87]

The entry of these therapeutically similar drugs acts as a powerful constraint on the pricing power of the incumbent brand-name manufacturer. In fact, a recent academic paper found that this type of "between-patent" competition among pharmaceutical firms actually restrains drug prices and revenue more than generic drug entry (on a present-value basis).[88] According to the paper's findings, between-patent entry reduces the present value of the incumbent drug's sales revenue by 17 percent, while generic, post-patent-expiration entry only

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[83] ITA.

[84] *Merck v. Integra*, 545 U. S. ___, 125 S. Ct. 2372 (2005).

[85] Abbott and Vernon.

[86] To understand why the risk-adjusted returns of less innovative products are higher than those associated with potentially revolutionary drug breakthroughs, one must consider that out of every 5,000 chemicals tested in animals, only five ever go on to human clinical testing, and only one of those ever goes onto the market.[86] Worse, only three out of every ten of the products that make it to market generate after-tax returns (measured in present-value terms) in excess of average, after-tax R&D costs. Moreover, the time it takes to develop these drugs (the time between the date that outlays are first expended for research and the date that the first dollar in sales is received) is about 15 years, on average. To illustrate this calculus, consider this stylized and highly-simplified example: A company is faced with a decision to spend $100 million to investigate a molecular compound that could yield a "blockbuster drug," with an estimated expected gross sales revenue of $40 billion, but only a 10 percent chance of receiving FDA approval, OR spending that $100 million to develop a compound that could yield a "me-too" drug that has an estimated expected gross sales revenue of $9 billion, but a 50 percent chance of being approved by the FDA and launched. The preferred initial investment would be in the "me-too" drug, with the profits likely to be reinvested in the higher-yielding blockbuster. Abbott and Vernon.

[87] CBO, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998.

[88] Frank R. Lichtenberg and Tomas J. Philipson, "The Dual-Effects of Intellectual Property Regulations: Within and Between Patent Competition in the U.S. Pharmaceutical Industry," *Journal of Law and Economics*, vol. XLV, October 2002.

reduces such revenue by 4 percent. This is because by the time a patent has expired, the influx of "between-patent" competitors has largely bid away the incumbents' excess returns, and because revenues lost to generics after patent expiration are discounted relative to revenues collected in the period immediately after launch.[89]

Conclusion

It is not "free trade" to compel a drug company to sell to countries that control prices so that a middleman company can mark up the drug and resell it to American consumers. Such a policy would actually replace competition between drug developers with compulsory importation of compulsory-priced drugs. It would not be long before the incentive to invest in the R&D necessary for new drug development would be lost, leaving U.S. consumers worse off in the long run, with reduced access to newer, innovative drugs. Instead of passing a bill to import foreign governments' price controls, the Senate should encourage the USTR to continue to press developed nations to eliminate price controls on innovative drugs under the guise of "public health" concerns. Real free trade would offer consumers in other countries the same new drugs available to U.S. consumers while reducing drug prices in the United States. It would also promote the growth of domestic jobs and investment provided by the U.S. pharmaceutical industry.

[89] The present value of a future cash flow is the nominal amount of money to change hands at some future date, discounted to account for the time value of money. A given amount of money is always more valuable sooner than later since this enables one to take advantage of investment opportunities. Because of this, present values are smaller than corresponding future values. For example, assuming a 10 percent interest rate, the present value of $500 million in revenues earned 10 years after launch would equal $192 million.